

Facility Name _____
Address _____ **Phone** _____
State License Number _____ **CLIA number** _____
Laboratory Director _____ **(print name)**
Laboratory Director Signature _____ **Date** _____

	EXEMPT LABORATORY ATTESTATION FORM				
TAG	REGULATION TEXT	Y	N	N/A	Comments
	Regulation NAC652.155 & NAC 652.175 A laboratory operated by a licensed physician pursuant to NRS 652.235 must register with the Health Division as an exempt laboratory – Check applicable: <ul style="list-style-type: none"> • Tests are “Waived” • Providers (MD, DO, PA, APN) perform PPM (Provider Performed Microscopy) & Waived tests • Collection only • Physician performs tests <i>Without Assistance</i> – on his own patients <i>If non-exempt, please use the Registered Laboratory application & attestation.</i>				
L0001	Regulation NAC652.155(2)(a) Type Rule Regulation Definition Interpretive Guideline Custom Help 2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory that is licensed by or registered with the health division pursuant to chapter 652 of NRS may perform a test without complying with the provisions of this chapter if: (a) The test has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; <ul style="list-style-type: none"> • <i>Do assistants perform waived testing?</i> 				

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L0002	Regulation NAC652.155(2)(b)(1) Type Rule Regulation Definition Interpretive Guideline Custom Help The director, a designee of the director or a licensed physician at the laboratory at which the waived test is performed: (1) Verifies that the person is competent to perform the test; <ul style="list-style-type: none"> <i>Are there training and competency assessment records for each assistant for all tests performed signed by the lab director or designee?</i> 				
L0003	Regulation NAC652.155(2)(b)(2) Type Rule Regulation Definition Interpretive Guideline Custom Help The director or a designee of the director at the laboratory at which the test is performed : (2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; <ul style="list-style-type: none"> <i>Are manufacturer's instructions followed step by step?</i> <i>Are written procedures available for each test? (manufacturer's package inserts are acceptable).</i> <i>Are kits/reagents are stored according to manufacturer's instructions?</i> <i>Is there a daily temperature log for room, refrigerator, and freezer (if applicable)? The correct temperature range must be established and noted on the log, and the daily temperatures must be within that range or corrective action must be taken.</i> <i>Are supplies used within current expiration dates? (No expired reagents/supplies should be in-use.)</i> <i>Are expiration dates modified after opening, when applicable?</i> <i>Is there a system in place to maintain positive patient identification throughout the testing process? Ex: name and date of birth, or unique patient ID number.</i> 				

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L0004	<p>Regulation NAC652.155(2)(b)(3) Type Rule Regulation Definition Interpretive Guideline Custom Help The director or a designee of the director at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.</p> <p><u><i>Two levels of control must be run each day of patient testing</i></u> <u><i>Internal, external and electronic controls are acceptable</i></u></p> <ul style="list-style-type: none"> ▪ <i>Are all controls, internal, external or electronic documented?</i> ▪ <i>Are the results of the controls within range per the package insert?</i> ▪ <i>Is the acceptable range for the controls, the lot numbers and expiration dates of the kit and controls, noted on the control log sheet with the daily results?</i> ▪ <i>Have trial controls been run and documented for each test kit?</i> 				
L0005	<p>Regulation NAC652.155(3)(a) Type Rule Regulation Definition Interpretive Guideline Custom Help 3. The provisions of subsection 2 do not relieve a person who performs a test from the requirement to: (a) Comply with the policies and procedures that the director</p>				

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	<p>of the laboratory at which the test is performed has established pursuant to NAC 652.280.</p> <p>NAC 652.280 Duties of director: Health and safety; physical premises and environmental conditions.</p> <p>A director shall ensure that:</p> <p>2. The physical premises and environmental conditions of the laboratory(b) Provide a safe environment in which employees are protected from biological, chemical, and physical hazards.</p> <p>4. Showers and eyewashes are provided where necessary for safety.</p> <p><i>This provision applies to safety in the laboratory area. Standard Precautions and safety policies must be enforced.</i></p> <ul style="list-style-type: none"> ▪ <i>Is there a written policy which prohibits eating, drinking, smoking and storage of food in the lab area?</i> ▪ <i>Is bio-hazardous waste disposed of properly?</i> ▪ <i>Are sharps disposed in puncture-proof containers? No bending, breaking or recapping of needles.</i> ▪ <i>Is there an eyewash (portable or fixed eyewash station) in or near the testing area?</i> ▪ <i>Is the lab adequately ventilated?</i> ▪ <i>Are temperatures controlled, monitored and recorded?</i> ▪ <i>Is lab area disinfected?</i> 				
L0121	<p>Regulation NAC652.155(3)(b)</p> <p>Type Rule</p> <p>Regulation Definition Interpretive Guideline Custom Help</p> <p>3. The provisions of subsection 2 do not relieve a person who performs a test of the requirement to:</p> <p>(b) Obtain certification pursuant to NAC652.470.</p>				

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	<p>1. Before working in a laboratory at any technical level: (a) An application for certification must be made on a form provided by the bureau giving information on the applicant's educational background; (d) A fee, which is not refundable, must accompany the Application. <i>This provision applies to <u>all</u> non-provider testing personnel (MA, LPN, RN) performing testing.</i> <ul style="list-style-type: none"> <i>Have testing personnel applied for, or do they possess, certification as Office Laboratory Assistant, unless otherwise indicated?</i> <i>Applicable fee must be paid.</i> </p>				
L0122	<p>Regulation NAC652.155(4)(a)(b) Type Rule Regulation Definition Interpretive Guideline Custom Help 4. An advanced practitioner of nursing as defined in NRS 632.012 or a physician assistant as defined in NRS 630.015 who is employed by a laboratory that is licensed by or registered with the Health Division pursuant to chapter 652 of NRS and who has not received certification pursuant to NAC 652.470 may perform a test without complying with the provisions of this chapter if the test: (a) Has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or (b) Is a provider-performed microscopy categorized pursuant to 42 C.F.R. § 493.19. <ul style="list-style-type: none"> <i>PAs and APNs can perform waived or PPM testing without obtaining additional personnel licensure from the State.</i> <i>Revision 7/15/10</i></p>				